K130663

Section 5. 510(k) Summary

510(k) SUMMARY

A 510(k) summary in accordance with the requirements of 21 CFR 807.92.

Submitter:	Curative Medical Inc. 3227 Kifer Road Santa Clara, CA 95051 Establishment Number: 3008361782
Company Contact Person: Phone: Fax: Email:	Cuong Tran, R/D Director (408) 414-2188 (408) 413-3000 ctran@curativemedical.com
Submission Correspondent: Address: Phone: Email:	Amy McKinney, Regulatory Affairs Consultant 6518 Tamarind Sky Ln., Fulshear, TX 77441 (979) 236-1622 amckinney29@att.net
Device Name:	BestFit™ Nasal Mask Models: • BestFit2 nasal mask, S (30120032) • BestFit2 nasal mask, M (30120022) • BestFit2 nasal mask, L (30120012) • BestFit nasal mask, S (30100030) • BestFit nasal mask, M (30100020) • BestFit nasal mask, L (30100010) • BestFit nasal mask, MW (30100040)
Device Classification Name:	Non-continuous ventilator (BZD) 21 CFR 868.5905
Predicate Devices:	Resmed Ultra Mirage II (K050359)
Preparation Date:	August 23, 2013

SEP 27 2013

Device Description:

The BestFit™ Nasal Masks are patient interface devices used on adult patients prescribed with CPAP and Bi-Level Positive Airway Pressure therapy. The BestFit product family consists of two models, BestFit and and BestFit 2. Both models have same function and performance, except for a slight difference in the forehead design. Both devices are vented and can be used multiple times in a hospital, clinical and/or home environment.

The nasal mask style covers and seals around the patient's nose and delivers positive pressure from the therapy device to the patient via the patient air circuit of the CPAP device. The BestFit Nasal Masks include the following accessories: headgear and Instructions for Use (IFU).

The model BestFit Nasal mask is available in 4 different sizes: Small (S), Medium (M), Large (L), and Medium Wide (MW). The model BestFIt 2 Nasal mask is available in 3 different sizes: Small (S), Medium (M), and Large (L).

The BestFit Nasal Masks have the following similarities to the previous cleared predicate device:

- Same intended use
- Same operating principle
- Similar technologies

Parameter	Resmed ultra Mirage II (K050359)	BestFit (both models)	Comparison
Therapy Pressure	4 – 20 cmH20	4 – 20 cmH20	Same
Pressure-Flow Curve	**Pressure (cm H2O) / Flow (lpm)** 4 / 18 8 / 29 12 / 38 16 / 46 20 / 53	**BESTFIT: Pressure cm H2O / Flow (lpm)** 4 / 17.87 8 / 28.94 12 / 37.88 16 / 45.25 20 / 52.12 **BESTFIT 2: Pressure cm H2O / Flow (lpm)** 4 / 16.59 8 / 26.92 12 / 35.18 16 / 42.60 20 / 49.28	Less flow with constant pressure – compliant with internal spec and ISO 17510-2 test procedure
Dead space Information	135 mL	BestFit: <160 mL BestFit 2: <165 mL	Larger – no clinical effect
Sound level (10 cmH20 & 1 Meter)	28 dbA	BestFit: <29 dbA BestFit 2: <30 dbA	Louder, compliant with ISO 17510-2 Annex G

Parameter	Resmed ultra Mirage II (K050359)	BestFit (both models)	Comparison
Resistance to Flow	At 50 lpm, 0.1 cmH20 At 100 lpm, 0.3 cmh20	50 lpm, 0.1 cmH20 100 lpm, 0.5 cmH20	Same at 50 lpm, more at 100 lpm, Compliant with ISO 17510-2 Annex C
Dimension (HxWxD mm)	163 x 91 x 87	155 x 98 x 95 (BestFit) 145 x 98 x 97 (BestFit2)	Similar, no clinical effect
Temperature (operating – °C)	3 – 35	3 – 35	Same
Mode operation compatibility	CPAP & BiLevel	CPAP & BiLevel	Same
Head Gear & Clip	• 2 at forehead • 2 at lower half • Adjustable	• 2 at forehead • 2 at lower half • Adjustable	Same
Cushion	4 sizes	BestFit – 4 sizes BestFit 2 – 3 sizes	Similar – support various sizes
Patient circuit Interface	22 mm conical	22 mm conical	Same
Swivel Patient circuit interface	Yes	Yes	Same
Support Daily Cleaning	Yes	Yes	Same
Support Disinfection	Yes	Yes	Same
Indications For Use	Intended for multipatient re-use for adult patients prescribed continuous positive airway pressure (CPAP) or bilevel therapy in hospitals, clinic and home environment	intended for multiple use on adult patients (body weight >30kg) prescribed with using continuous positive airway pressure (CPAP) or bi-level ventilator system in hospital, clinic and/or home environment	Essentially identical

Intended Use:

The BestFit™ Nasal Masks are intended for multiple use on adult patients (body weight >30kg) prescribed with using continuous positive airway pressure (CPAP) or bi-level ventilator system in hospital, clinic and/or home environment.

Summary of Performance Data and Substantial Equivalence:

The BestFit™ Nasal Masks were designed and verified in accordance with the risk analysis and product requirements. All tests confirmed the products met the pre-defined acceptance criteria. Curative Medical Inc. has determined that the BestFit Nasal Masks are substantially equivalent to the predicate when used with CPAP and Bi-Level pressure therapy devices. The BestFit Nasal Masks have been tested and shown to be compliant with the following standards documents:

- ISO 17510-2: 2007- Sleep Apnoea Breathing Therapy – Part 2 Masks and application accessories
- ISO 10993-1:2009 – Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process
- ISO 10993-3:2003 - Biological Evaluation of Medical Devices – Part 3: Genotoxicity, Carcinogenicity and Reproductive Toxicity
- ISO 10993-5: 2009 - Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity
- ISO 10993-6:2007 - Biological Evaluation of Medical Devices – Part 6: Test for local effect after implantation
- ISO 10993-10:2010 – Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization
- ISO 10993-10:2002/Amend 1:2006 – Biological Evaluation of medical devices Part 10: Tests for irritation and skin sensitivity
- ISO 5356-1:2004 - Anaesthetic and Respiratory equipment conical connectors – part 1: Cones and sockets

This 510(k) submission presents the results of the following testing and detailed descriptions to demonstrate that BestFit Nasal Mask is substantially equivalent to the Resmed Ultra Mirage II Nasal Mask (K050359):

- Sound Test – Tested sound requirements in accordance with ISO 17510-2: 2007 standard
- Predicate Comparison Testing – Comparative testing of BestFit Nasal Masks to predicate device, Resmed Mirage II
- Packaging Testing - Tested packaging integrity in accordance with ISTA – 2A – 2008
- System Test Protocol and Report – Tested to ensure compliance with product specifications and product risk analysis
- Cleaning and Disinfection – Test to ensure compliance and survived daily cleaning and disinfection procedures
- Biocompatibility – Tested to ensure materials are biocompatible in compliance with ISO 10993-1

Testing was conducted to demonstrate the performance of BestFit™ Nasal Masks are substantially equivalent to the predicate device in their intended environment.

Conclusion:

The information and data provided in this 510(k) Notification establishes that the BestFit Nasal masks are substantially equivalent to their legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 27, 2013

Curative Medical, Incorporated
C/O Ms. Amy E. McKinney, MS, RAC
Regulatory Affairs Consultant
6518 Tamarind Sky Lane
FULSHEAR TX 77441

Re: K130663
Trade/Device Name: BestFit™ Nasal Mask and BestFit2™ Nasal Mask
Regulation Number: 21 CFR 868.5905
Regulation Name: Non-continuous ventilator
Regulatory Class: II
Product Code: BZD
Dated: August 26, 2013
Received: August 27, 2013

Dear Ms. McKinney:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

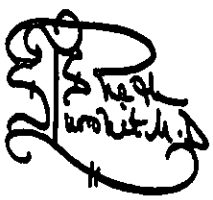
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
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FOR

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4. Indications for Use Statement

510(k) Number (if known): K130663

Device Name: BestFit Nasal Mask and BestFit2 Nasal Mask

Indications For Use:

The BestFit™ and BestFit™2 Nasal Masks are intended for multiple use on adult patients (body weight >30kg) prescribed with using continuous positive airway pressure (CPAP) or bi-level ventilator system in hospital, clinic and/or home environment.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anya C. Harry-S

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices
510(k) Number: K130663